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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,083

10/22/2003

William Martin Belef

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IP PROSECUTION DEPARTMENT
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EXAMINER

GANESAN, SUBA

ART UNIT

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3774

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/692,083	Applicant(s) BELEF ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal brief filed on 9/04/07, PROSECUTION IS HEREBY REOPENED.

New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738

Response to Arguments

1. Applicant's arguments with respect to claims 1-12 have been fully considered but they are not persuasive. Applicant argues that the opening in the annulus fibrosis of Lambrecht is not created but is a pre-existing defect. The examiner disagrees, since the

opening exits, it has been created; *when* the opening was created is not a claimed limitation. Applicant further argues that the defect is never closed but rather is only blocked with a barrier. The examiner considers blocking an opening with a barrier to be the same as closing an opening (much the same as a door closes a doorway).

2. Applicant's arguments with respect to claims 13-33 have been considered but are moot in view of the new ground(s) of rejection.

3. It is noted that Lambrecht is maintained in the rejection only for teaching the use of energy to close a defect in the annulus fibrosis.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims **1-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Lambrecht et al. (U.S. Pat. No. 6,482,235).

Lambrecht et al. discloses a method for augmenting an intervertebral disc in order to repair defects in the annulus fibrosis including creating an opening through the annulus fibrosis into the interior of the disc (see figure **19**). Regarding claims 1-4, Lambrecht discloses removing a portion of the nucleus pulposus (col. 17 lines 4-7), introducing an implanted barrier (**12**). The barrier (**12**) is considered to be a therapeutic agent.

Lambrecht further discloses using radio frequency energy (col. 20, line 29) by introducing an 'elongate member' (**130**) with electrodes disposed on its distal portion,

those electrodes being activated while the elongate member is within the interior of the disc. With respect to claim 6, a distal end of a needle is used to deliver barrier (12) (see fig. 29 A-D). A thermal device (150) is attached to the elongate member (130) that delivers electrical energy to the surrounding tissue in order to close the passage (see fig. 29 D). With respect to claim 12, Lambrecht discloses a secondary object (418) that is a handle member that has an electrically conductive filament (col. 27 lines 38-44).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht '235 in view of Underwood et al. (U.S. Pat. No. 6,929,640).

Lambrecht is explained as above. Lambrecht does not disclose the injection of a therapeutic agent using a syringe, or disconnecting the syringe before connecting a handle member to the needle. However, it would have been a matter of obvious design choice to one of ordinary skill in the art to utilize a syringe to deliver a therapeutic agent and further to disconnect the syringe before connecting a handle member, since it is well known in the art that syringes deliver therapeutic material, and that therapeutic materials are utilized in surgical procedures. It would have further been an obvious design choice to disconnect the syringe before connecting a handle member for the purpose of manipulating the needle.

5. Claims **15-17, 20-21, 23, and 27-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning (U.S. Pat. No.3,875,595) in view of Ferree (WO 01/10316) further in view of Lambrecht '235.

Froning discloses a method of treating a spine, including the steps of removing at least portion of the nucleus pulposus from an interior region of a spinal disc to define a space; lining the space with a nonporous liner material or bladder (**46**); and filling the space with a fill material or fluid to expand the liner material (see Figures 1-8). The bladder includes a neck with an opening and a sealing member. However, Froning does not disclose the liner material being bioabsorbable, the use of energy to close the opening in the annulus fibrosis or the fill material used in the method being the nucleus pulposus from the disc.

Ferree discloses a method of treating a spine including removing at least a portion of the nucleus pulposus, lining the space with a liner or bladder and filling the space with a fill material or fluid to expand the liner material (See abstract). Froning also teaches that any of the disclosed configurations may be made of bioabsorbable materials (pg. 17 line 18-pg. 18 line 4) and use of the device to retain therapeutic materials including cultured disc cells (pg. 18 lines 1-4).

Lambrecht '235 is explained supra. Furthermore, Lambrecht teaches the use of energy to close an opening in the annulus fibrosis.

One of ordinary skill in the art, equipped with the disclosure of Froning would have recognized the desirability of improving the nucleus pulposus replacement material to be more like the natural nucleus pulposus. Ferree suggests the use of

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cultured disc cells within the prosthetic liner or bladder as well as use of resorbable materials. One of ordinary skill in the art, equipped with the disclosure of Ferree would have recognized the desirability of utilizing a patients own disc cells (i.e. nucleus pulposus material) for the purpose of avoiding homologous or heterologous reactions (by using autologous material). Furthermore, one of ordinary skill in the art would understand that the closest approximation to nucleus pulposus material would be nucleus pulposus. It is further understood that the teaching of Ferree to include therapeutic materials would have suggested one of ordinary skill in the art to use concentrated growth factor derived from plasma (for example platelet derived growth factor) as the therapeutic material of choice. Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to try the use of autologous nucleus pulposus as a filler material for a prosthetic bladder or liner, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Froning and Ferree do not disclose the use of energy to the annulus fibrosis to close an opening. Lambrecht teaches the use of applying thermal or radiofrequency energy to close an opening in the annulus fibrosis. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize energy as a means of closing a defect in the annulus fibrosis as taught by Lambrecht to close a defect occurring with the methods of Froning and Ferree. Using a known technique of applying energy to provide a closed defect in the annulus fibrosis would have been obvious because the technique for improving a particular class of devices of

part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

6. Claim **18-19**, and **24-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning (U.S. Pat. No.3,875,595) in view of Ferree (WO 01/10316) in view of Lambrecht '235 as applied to claim 15 above, and further in view of Carr Jr. et al. (U.S. Pat. No. 5,733,337). Froning in view of Lambrecht discloses same as above.

7. However, Froning in view of Ferree and Lambrecht suggests a bladder or fill material of therapeutic materials. However, the references do not specifically teach a bladder or fill material comprised of at least one of intestinal submucosa, stomach submucosa, or bladder submucosa. Carr Jr. et al. discloses the use of intestinal submucosa (col. 2-3, lines 66-3) for biodegradable implantation within the body. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Froning in view of Ferree and Lambrecht to further include the use of intestinal submucosa for the purpose of making the implant or fill biodegradable. It is also noted that intestinal submucosa comprises an extra-cellular matrix material.

8.

9. Claim **22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Froning (U.S. Pat. No.3,875,595) in view of Ferree (WO 01/10316) in view of Lambrecht '235 as applied to claim 15 above, and further in view of Felt et al. (U.S. Pat. No. 6,140,452).

10. Froning in view of Ferree and Lambrecht discloses same as above. However, Froning in view of Ferree and Lambrecht does not disclose filler material comprising an

interpenetrating polymer network material. Felt et al. teaches the use of an interpenetrating polymer network (for example, see col. 30 lines 36-40) in order to utilize a multiphasic bulk morphology. Therefore it would have been obvious to one of ordinary skill in the art to modify Froning in view of Lambrecht with the interpenetrating network of Felt et al. in order to have a filler material with multiphasic bulk morphology.

11.

12. Claims **30-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning (U.S. Pat. No.3,875,595) in view of Ferree (WO 01/10316) further in view of Lambrecht '235 as applied to claim 27 above, and further in view of Michelson (U.S. Patent 4,968,298).

Froning, as applied to claim **27**, discloses the claimed invention except for the step of introducing a flowable fill material into the interior region of the disc before introducing the lining. Michelson teaches to irrigate or wash out disc interspace after the material from the disc has been removed, in order to remove any disc fragment and prevent inflammation of the neural elements and/or further surgery (see col. 1 line 5, through col. 2 line 46). It would have been obvious to one skill in the art at the time the invention was made to practice the method of Froning including the step of irrigate or wash out the interior region of the disc in view of Michelson, in order to be sure that no fragments of the nucleus pulposus are left inside the disc thus preventing inflammation and/or further surgery. With regard to claims **31-33**, it would have been further obvious to one having ordinary skill in the art at the time the invention was made to irrigate or wash out the interior of the disc with naturally occurring extra-cellular matrix material, a

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slurry of at least one of saline, an antibiotic, a steroid, and a non-steroidal anti-inflammatory drug, or an autologous therapeutic agent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suba Ganesan/
Examiner, Art Unit 3774

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738